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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09.055.145	04/03/1998	DONALD P. WEEKS	3553-18	3535

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

28

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/055,145

Applicant(s)

WEEKS ET AL

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 21-24, 36-39, 44, 47, 48 and 50-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7, 21, 24, 36, 39, 44, 47, 48, 50-52, 54-56 and 58-68 is/are rejected.
- 7) ☒ Claim(s) 3, 6, 22, 23, 37, 38, 53 and 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office action is in response to the Amendment and Response filed 18 December 2002.
2. New claims 66-68 have been added as requested.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 1, 2, 4, 5, 7, 21, 24, 36, 39, 44, 47, 48, 50-52, 54-56 and 58-65 remain rejected and claims 66-68 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 July 2002. Applicant's arguments filed 18 December 2002 have been fully considered but they are not persuasive.

Applicant argues that the specification describes variants of the exemplified sequence, including sequences that have one or more amino acid deletions and homologues of the exemplified sequences having 65%-85% identity to the claimed sequence, how percent identity between two sequences can be determined and how molecular techniques can be used to identify and isolate additional clones from

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organisms other than the ones from which the clones were originally isolated (paragraph spanning pages 8-9 of the Response). This argument is not found to be persuasive because pages 8-11 only describe how one of skill in the art could isolate other dicamba-degrading oxygenases, or modify the exemplified dicamba-degrading oxygenase. The Examiner maintains that the instant specification does not adequately describe the claimed isolated DNA molecules within the breadth of the claimed invention. See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself".

Applicant argues that the specification shows how the biological activity of an oxygenase of the invention can be evaluated and provides guidance to those of skill in the art regarding conserved structural features that would readily allow one of skill in the art to recognize what changes could be made to a given oxygenase which would not be expected to destroy the biological activity of the oxygenase, for example iron-sulfur cluster(s) or heme groups(s) which are structural features known to be possessed by some oxygenases (page 9, 1st paragraph of the Response). This argument is not found to be persuasive because the "features" described in the instant specification are common to other P450 oxygenases, and are not special technical features of dicamba-degrading oxygenases.

Applicant argues that the exemplification and description of the oxygenase that is recited in Claim 1 and related claims provides a clear written description that is sufficient

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to distinguish it from other proteins and convey to the skilled artisan that Applicants were in possession of such oxygenases at the time of the invention (page 10, 2nd paragraph of the Response). This argument is not found to be persuasive because Applicant has only described one isolated DNA molecule encoding a dicamba-degrading oxygenase, isolated from a single organism, that being *Pseudomonas maltophilia*, and does not describe the claimed genus of dicamba-degrading oxygenases encoding DNA molecules. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Applicant argues that the evidence presented in the Weeks Declaration filed 30 July 2002 shows that a probe spanning 900 out of the 1020 bp of the exemplified dicamba-degrading oxygenase DNA hybridizes to DNA from each of three different dicamba-degrading bacterial strains, including strains from a different genus than *Pseudomonas*, and that given the hybridization conditions and the size of the probe, it was estimated that the DNA that was hybridized in these strains had greater than 90%

identity to the probe DNA (paragraph spanning pages 10-11 of the Response). This argument is not found to be fully persuasive because the Examiner maintains that the Weeks Declaration (July 2002) only provides asserted evidence of a possible function, and sequence similarity, and not conclusive evidence thereof. In addition, the evidence of the Weeks Declaration (July 2002) is not commensurate with the breadth of the claims. Hence, this evidence does not satisfy the requirement for an adequate written description of the claimed genus as outlined in the previous paragraph.

Applicant argues that the description of the DNA sequence encoding an oxygenase from a dicamba-degrading bacterium is not merely a description based on function because the source of the protein is identified and because the specification clearly describes the structural, biochemical and physical properties of such an oxygenase (page 11, 3rd paragraph of the Response). This argument is not found to be persuasive. In the decision of *University of California V. Eli Lilly and Co*, the University of California had only isolated and described a rat cDNA encoding an insulin protein, yet one of skill in the art at the time of the invention would have clearly recognized that other mammals produce insulin proteins, yet the court determined that a description of just one example of a cDNA encoding an insulin protein did not adequately describe the genus of mammalian insulin encoding cDNAs.

6. Claims 1, 2, 4, 5, 7, 21, 24, 36, 39, 44, 47, 48, 50-52, 54, 55 and 58-65 remain rejected and claims 66-68 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the DNA molecule of SEQ ID NO: 3, DNA molecules encoding the dicamba-degrading oxygenase of SEQ ID NO: 4, methods of

using said DNA molecules and plants comprising said molecules, does not reasonably provide enablement for any DNA molecule encoding a dicamba-degrading oxygenase within the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 July 2002. Applicant's arguments filed 18 December 2002 have been fully considered but they are not persuasive.

Applicant argues that the issue of the present invention is whether a single enzyme can act on a single substrate, dicamba, which is one substrate within the class of benzoic acid herbicides, and that the teachings of Siminszky *et al* (1999) is not relevant in the instant case (paragraph spanning pages 12-13 of the Response). This argument is not found to be persuasive because the Examiner notes that claims 2 and 5, as an example, do not specify a specific activity of the encoded dicamba-degrading oxygenase. The example of Siminszky teaches that even though a P450 oxygenase reacts with a compound, there can be no expectation of a useful function. Hence, Applicant has failed to teach one of skill in the art at the time of the invention how to make and use the invention within the scope of the claims.

Applicant argues that Applicants have demonstrated that an oxygenase that degrades dicamba confers dicamba resistance on a host transformed with the oxygenase and that there is no need to screen through all dicamba-degrading oxygenases to see whether they confer resistance or not (page 13, 1st paragraph of the

Response). This argument is not found to be persuasive for the reason given above.

The example of Siminsky teaches that just because a P450 oxygenase can react with a compound, such as dicamba, does not inherently teach a useful function, such as conferring resistance to dicamba on a transformed host cell.

7. The Weeks Declaration under 37 CFR § 1.132 filed 18 December 2002 is insufficient to overcome the rejection of claims 1, 2, 4, 5, 7, 21, 24, 36, 39, 44, 47, 48, 50-52, 54-56, 58-65 and 66-68 based upon 35 U.S.C. § 112, first paragraph, as set forth in the last Office action for the reasons give above. The arguments have been fully considered but the Examiner does not consider the argument sufficient to overcome the issue of written description and the scope of enablement in the instant case.

Allowable Subject Matter

8. Claims 3, 6, 22, 23, 37, 38, 53 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
4 March 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

